



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Biologics Evaluation and Research
1401 Rockville Pike
Rockville MD 20852-1448

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• Mr. Thomas J. Bucknum
Biogen, Inc.
Fourteen Cambridge Center
Cambridge, MA 02142

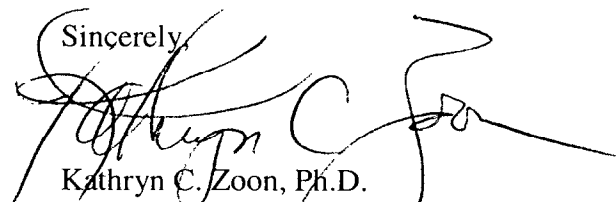
Re: Docket No. 02P-0154/CP1

Dear Mr. Bucknum:

Pursuant to 21 CFR 10.30(e)(2), this letter is a tentative response to your citizen petition dated April 12, 2002, that was filed with the Dockets Management Branch on April 15, 2002. Your petition requested that the Commissioner of Food and Drugs take the following actions: (1) Assure that labeling of Serono, Inc.'s, interferon beta-1a product, REBIF®, and any promotional or advertising materials for such products are neither false nor misleading by requiring Serono, Inc., to supplement existing information in the label about the relative efficacy of REBIF® and Biogen's AVONEX® (interferon beta-1a) products from the first 24 weeks of Serono's 48-week EVIDENCE trial with data on the relative efficacy of the two products gathered during the second 24-week period of the trial; (2) Correct errors in the discussion on neutralizing antibodies contained in the publicly available analysis document prepared by the Center for Biologics Evaluation and Research (CBER) in connection with the approval of REBIF®; (3) Further investigate the manner in which Serono conducted the EVIDENCE trial, particularly whether its conduct of the trial introduced bias into reporting of exacerbations in the treatment groups and further that the Food and Drug Administration (FDA) monitor Serono's conduct of upcoming Phase IV trials.

Your petition is currently under FDA review. We will respond to your petition after completing our evaluation of the information you have submitted.

Sincerely,



Kathryn C. Zoon, Ph.D.
Director, Center for Biologics
Evaluation and Research

cc: Dockets Management Branch (HFA-305)

02P-0154

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